



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Artificial Intervertebral Disc: Lumbar Spine

**Policy #** 00145

**Original Effective Date:** 01/31/2005

**Current Effective Date:** 01/15/2014

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

**Note:** Artificial Intervertebral Disc: Cervical Spine is addressed in medical policy number 00229.

### **Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers artificial intervertebral discs of the lumbar spine to be **investigational**.\*

### **Background/Overview**

Total disc replacement, using an artificial intervertebral disc designed for the lumbar spine, is proposed as an alternative to fusion in patients with persistent and disabling nonradicular low back pain.

When conservative treatment of degenerative disc disease fails, a common surgical approach is spinal fusion; more than 200,000 spinal fusions are performed each year. However, the outcomes of spinal fusion have been controversial over the years, in part due to the difficulty in determining if a patient's back pain is related to degenerative disc disease (DDD) and in part due to the success of the procedure itself. In addition, spinal fusion alters the biomechanics of the back, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, a variety of artificial intervertebral discs have been investigated as an alternative approach to fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed and to maintain the normal biomechanics of the adjacent vertebrae.

Potential candidates for artificial disc replacement have chronic low back pain attributed to DDD, lack of improvement with non-operative treatment, and none of the contraindications for the procedure, which include multilevel disease, spinal stenosis, or spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. These contraindications make artificial disc replacement suitable for a subset of patients in whom fusion is indicated. Patients who require procedures in addition to fusion, such as laminectomy and/or decompression, are not candidates for the artificial disc.

Use of a motion-preserving artificial disc increases the potential for a variety of types of implant failure. These include device failure (device fracture, dislocation, or wear), bone-implant interface failure (subsidence, dislocation-migration, vertebral body fracture), and host response to the implant (osteolysis, heterotopic ossification, and pseudotumor formation).



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## **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

While artificial intervertebral discs in the lumbar spine have been used internationally for more than 10 years, only 2 devices (Charité<sup>®i</sup> and ProDisc<sup>®i-L</sup>)<sup>‡</sup> have received approval from the U.S. FDA. Because the long-term safety and effectiveness of these devices were not known, approval was contingent on completion of postmarketing studies. The Charité (DePuy) and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with DDD at one level; Charité is approved for use in levels L4–S1, and the ProDisc-L is approved for use in levels L3–S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. The INMOTION<sup>® ‡</sup> lumbar artificial disc (DePuy Spine) is a modification of the Charité device. Production of the Charité disc was stopped in 2010. Other devices are currently under investigation in the U.S. as part of the FDA process of approval, including the FlexiCore (Stryker Spine), Maverick (Medtronic), and Activ-L<sup>™ ‡</sup> (Aesculap) devices.

Centers for Medicare and Medicaid Services (CMS)

Effective for services performed from May 16 through August 13, 2007, the CMS found that lumbar artificial disc replacement (LADR) with the Charite lumbar artificial disc is not reasonable and necessary for the Medicare population over 60 years of age. Therefore, CMS issued a national non-coverage determination for LADR with the Charité lumbar artificial disc for the Medicare population over 60 years of age.

Effective for services performed on or after August 14, 2007, CMS found that LADR is not reasonable and necessary for the Medicare population over 60 years of age; therefore, LADR is non-covered for Medicare beneficiaries over 60 years of age. For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination, leaving such determinations to be made by the local contractors.

The national coverage determination was revised in 2007 to reflect a change from non-coverage for a specific implant (the Charité), to non-coverage for the lumbar artificial disc replacement procedure for the Medicare population older than 60 years of age. CMS provided this explanation, “The original NCD [national coverage determination] for LADR was focused on a specific lumbar artificial disc implant (ChariteTM) because it was the only one with FDA approval at that time. In the original decision memorandum for LADR, CMS stated that when another lumbar artificial disc received FDA approval CMS would reconsider the policy. Subsequently, another lumbar artificial disc, ProDisc-L, received FDA approval, which initiated the reconsideration of the NCD on LADR. After reviewing the evidence, CMS is convinced that indications for the procedure of LADR exclude the populations older than age 60; therefore, the revised NCD addresses the procedure of LADR rather than LADR with a specific manufacture’s implant.”

## **Rationale/Source**

When this policy was created in 2003, the only evidence available was several case series describing the international experience with the SB Charité device. In the largest case series, which included 105 patients, 79% of patients reported an excellent result at a mean follow-up of 51 months. Another case series with 56 patients also reported significant improvement in pain and function. However, case series data provide little evidence of efficacy, particularly in the case of back pain due to degenerative disc disease where outcomes can be influenced by patient selection, placebo effects, or natural history.

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In February 2005, TEC completed an assessment of artificial disc replacement, focusing on the Charité lumbar disc device. Only 1 completed randomized clinical trial had evaluated the Charité artificial disc compared to the BAK fusion cage for the treatment of single-level DDD. The ProDisc, FlexiCore, and Maverick devices were also undergoing investigation in similarly designed randomized trials. The 2005 TEC Assessment concluded that, compared with fusion or other treatments, evidence supporting the effectiveness of artificial vertebral discs in terms of pain relief and restoration of function among patients with chronic discogenic low back pain was insufficient.

In August 2006 the ProDisc-L was approved by the U.S. FDA. An updated TEC Assessment in February 2007 reviewed the evidence on artificial lumbar disc replacement devices. No additional randomized controlled trials (RCTs) had been published since the FDA approval of the ProDisc-L in 2006. The Assessment found that both the Charité and ProDisc-L trials had been evaluated with one randomized clinical trial, designed as a noninferiority trial, with the comparator being fusion. TEC noted that the validity of a noninferiority trial rests on several assumptions.

- First, the comparator treatment should have well-known and precise knowledge of effectiveness compared to no treatment. This knowledge and the noninferiority margin designated for the trial should assure that the new treatment is superior to no treatment. In the case of fusion, there are few clinical trials, and results are inconsistent. Neither of the reports discussed the effectiveness of fusion or justified the size of the noninferiority margin.
- Second, the trial should achieve historical levels of effectiveness in the known comparator. The lower-than-expected success rates of fusion in Charité and ProDisc-L trials raise additional questions regarding the validity of a noninferiority trial and the noninferiority margin selected. Viewed from the perspective of superiority trials, both trials are also suspect. The Charité trial showed little evidence of superiority, and the ProDisc analysis is problematic because of missing values and uncertain outcomes for all patients.
- Finally, an acceptable margin of inferiority is reasonable for a new treatment if there are obvious advantages of the new treatment, such as patient acceptability, convenience, invasiveness, or cost. Given the invasiveness of the procedure, there are no obvious short-term advantages. In terms of the long-term goal of reducing stress on adjacent levels, the duration of follow-up was insufficient for evaluation.

The Assessment concluded that given what is known about fusion as a comparator treatment, neither of the noninferiority trials provided convincing evidence of efficacy. TEC concluded that the evidence supporting the effectiveness of the ProDisc -L and Charité artificial disc was limited and that there was no immediately discernible advantage to use of the artificial disc.

In 2010, 2 systematic reviews concluded that high-quality RCTs with a relevant control group and long-term follow-up are needed to evaluate the effectiveness and safety of artificial lumbar disc replacement. Following is a summary of key literature to date.



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## **Charité (INMOTION)**

The Charité device has been withdrawn from the market. The INMOTION artificial disc is a modification of the Charité design.

Controlled Trials. The pivotal study for the Charité device consisted of a randomized clinical trial comparing the artificial intervertebral disc to spinal fusion using a threaded fusion cage with autologous bone graft. Patients were randomly assigned in a 2:1 fashion, with 205 receiving the artificial disc and 99 undergoing fusion. In this trial's analysis of 267 patients followed up for up to 24 months, the Charité artificial disc had a success rate of 63% compared to a success rate of 53% for BAK [Bagby and Kuslich] fusion, using a composite measure of outcomes that incorporated improvement of symptoms and absence of complications. The analysis showed noninferiority compared to BAK fusion using the composite measure of success but did not show statistically significant superiority in most outcome measures. The point estimate of 63% success did not show the artificial disc to be a highly successful treatment. In addition, the long-term effectiveness and health outcomes for artificial vertebral discs were uncertain.

In 2008, Guyer and colleagues reported 5-year follow-up of a subset of the patient cohort that had participated in the investigational device exemption (IDE) trial of the Charité artificial disc (described above). Of the initial 14 sites, 6 declined participation in the 5-year continuation study, and an additional 8 patients were excluded from analysis, leaving 233 patients from the original randomized study. There were 133 cases included in the 5-year assessment (57% from the 8 sites). Based on denominator of 375 patients originally enrolled in the IDE trial, this report represents 30% of the study population. Given the limitations of the original RCT and the 50% to 70% loss to follow-up, results from the 5-year follow-up cannot be interpreted.

Observational Studies. Mean 17.3 year (range, 14.5-19.2 years) follow-up was reported for Charité types I – III intervertebral discs from the Charité hospital. For the 53 of 71 patients (75%) who were available for clinical and radiologic examination, there were 16 type I discs (1984-1985), 25 type II discs (1985-1987), and 22 type III discs (1987-1989). The type III prosthesis is the model that is currently available. Clinical evaluation at follow-up showed no significant difference between the 3 types of discs for the Oswestry disability index (ODI), visual analog scale (VAS) for pain, or overall outcome score. Out of the 53 patients, 12 (23%) had a segmental fusion during follow-up due to implant failure or pain. Seven of the 12 (58%) were due to implant fractures, and 5 underwent secondary operative instrumented spondylodesis. Out of the remaining 41 patients, 9 (17% of 53) showed no signs of heterotopic ossification or ankylosis at follow-up while ankylosis was observed in 32 patients (60%) after 17 years. No signs of adjacent segment degeneration were found in the 9 cases (17%) without signs of ankylosis, spondylodesis, or implant failure. Although no adjacent segment degeneration was observed in the small percentage of implants that remained functional (17%), these patients were significantly less satisfied than those with spontaneous ankylosis based on the ODI (52 vs. 38) and VAS (6.1 vs. 4.5). The authors, who had designed the prosthesis, concluded that this study demonstrated dissatisfying results after artificial disc replacement in the majority of the evaluated cases regarding clinical, as well as radiologic outcomes.

Scott-Young et al. reported average 45-month follow-up (range 2 to 10 years) from a consecutive series of 122 patients who received a single-level Charité disc. VAS back scores decreased from 78.2 preoperatively to 21.9 at final follow-up. ODI scores decreased from 51.1 to 16.2, and Roland-Morris Questionnaire scores

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decreased from 16.7 to 4.2. Short Form-36 (SF-36) physical component scores increased from 25.7 to 46.4, and SF-36 mental component scores increased from 35.5 to 51.6. In this prospective study, 91% of patients rated their satisfaction with the surgery as “excellent” or “good” at 2 years. There were 4 (3.3%) complications that required revision with fusion. Heterotopic bone formation was reported in 6 cases (4.9%). This series is limited by loss to follow-up, with outcomes reported from 70 patients (57%) at 2 years, 18 patients (15%) at 5 years, and 3 patients (2%) at 7 years.

Long-term follow-up in a larger number of patients is needed to answer questions regarding the potential for device failure, decay, wear, and facet degeneration.

## **ProDisc-L**

Controlled Trials. The pivotal study for the ProDisc-L was a randomized unblinded clinical trial of 242 patients followed up for 24 months. Patients were originally randomized in a 2:1 ratio to ProDisc-L artificial disc replacement (n=161) or circumferential fusion (n=75). Using an FDA-requested composite measure of outcome that incorporated symptom improvement and absence of complications, the ProDisc-L had a success rate of 53.4% and fusion had a success rate of 40.8%. This met pre-specified criteria for a noninferiority margin of 10% and just achieved statistical significance for a one-sided statistical test of superiority with a  $p=0.0438$ . The calculations were based on between 88% and 91% of randomized patients—how or which patients were censored was not described. Twenty-four month results from this trial were published in 2007. The published 24-month report included 236 patients but did not provide information about the number of patients lost to follow-up. The report included alternative definitions of overall success, which resulted in a greater difference between the two groups (experimental group 63.5%, control group 45.1%,  $p=0.005$ ). Five-year results were presented in abstract form in 2008, and in 2012, one of the investigators published a summary of the overall trial results at 2 and 5 years. The 5-year results have not been published as a full-length article by the research group. Out of an original 236 patients randomized, 193 (81.8%) were included in the 5-year follow-up (137 ProDisc-L and 56 controls). Results showed non-inferiority, but not superiority of artificial disc replacement, with 53.7% of ProDisc-L patients and 50.0% of fusion patients achieving overall success at 5 years. This change in overall success in ProDisc-L patients between 2 and 5 years (63.5% to 53.7%, respectively) indicate a possible decrement in response over time with the artificial disc. This decrement in response rate was not observed in the standard fusion group and resulted in convergence of the primary outcome measures between groups over time.

Several of the individual components of the primary outcome measure were also statistically better in the ProDisc-L group at 2 years, but were no longer significantly different at 5 years. For example, at 5 years ODI scores improved by 15% or more in 78.6% of ProDisc-L patients compared to 76.5% of controls. A similar percentage of patients maintained or improved SF-36 physical component scores compared with baseline (81.3% ProDisc-L and 74.0% fusion), and overall neurologic success was obtained in 88.8% of ProDisc-L patients and 89.6% of fusion patients. Secondary surgeries at the index level occurred in 8% of ProDisc-L patients and 12% of fusion patients ( $p$  value not reported). Device success, defined as the absence of any reoperation required to modify or remove implants and no need for supplemental fixation, was achieved in 93.3% of ProDisc-L patients and 93.2% of fusion patients. Analysis of VAS for pain excluded patients who had secondary surgical interventions (11 ProDisc-L and 5 fusion). For the ProDisc-L

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group, VAS improved from a mean of 75.9 at baseline to 37.1 at 5 years. Mean VAS for the fusion group improved from 74.9 at baseline to 40.0 at 5 years. There was no significant difference in VAS between the groups. Narcotic use decreased from a baseline of 84% to 44.6% of ProDisc-L patients and from 76% to 42.5% of fusion patients.

The ProDisc-L for 2-level lumbar degenerative disease was reported in 2011 from a multicenter randomized FDA-regulated non-inferiority trial. All patients in the study had DDD at 2 contiguous vertebral levels from L3 to S1 with or without leg pain, a minimum of 6 months of conservative therapy, and a minimum ODI score equal to or greater than 40. A total of 237 patients were treated in a 2:1 ratio with total disc arthroplasty or open circumferential arthrodesis (performed through both anterior and posterior open incisions). Postoperative evaluations were performed at 6 weeks and at 3, 6, 12, 18, and 24 months postoperatively. The total disc replacement group had decreased operative times (160.2 vs. 272.8 min), estimated blood loss (398.1 vs. 569.3 mL), and length of hospital stay (3.8 vs. 5.0 days). At 24 months, 58.8% patients in the ProDisc-L group and 47.8% patients in the arthrodesis group achieved the criteria for success, demonstrating non-inferiority but not superiority. The ProDisc-L group showed significant benefit in percentage improvement in the ODI (52.4% vs. 40.9%), a greater percentage of patients who achieved equal to or greater than 15-point improvement in the ODI (73.2% vs. 59.7%), the SF-36 physical component score (43.9 vs. 39.2), and 6-month neurologic success (87.3% vs. 71.6%). A greater percentage of patients in the arthrodesis group required secondary surgical procedures (8.3% vs. 2.4%). As noted in an accompanying commentary, there are a number of limitations to this study. Comparison with a procedure (open 360-degree fusion) that is not the gold standard precludes decisions on the comparative efficacy of this procedure to the standard of care. Other limitations include the relatively short follow-up and lack of blinding of both patients and providers.

Observational Studies. One case series was identified that followed up 55 patients for an average of 8.7 years after disc replacement with the ProDisc-L; 60% of patients report an excellent result. Additional publications report on the implantation of artificial discs at 2 levels in the lumbar spine.

## **Maverick**

In 2011, Gornet et al. reported 24-month results from a FDA-regulated multicenter IDE randomized non-blinded trial of the metal-on-metal Maverick artificial disc. A total of 577 patients were randomized in a 2:1 ratio to the Maverick disc (n=405) or to anterior interbody fusion with INFUSE Bone Graft and tapered fusion cages (n=172). All patients underwent a single-level, open anterior surgical procedure between the L4 and S1 level. The Maverick group had longer surgical times (1.8 vs. 1.4 hours) and greater blood loss (240.7 mL vs. 95.2 mL). Hospitalization stays were similar for both groups (2.2 vs. 2.3 days for fusion). At 24 months, radiographic fusion was observed in 100% of the control patients. Heterotopic ossification was observed in 2.6% of patients with the artificial disc. The FDA-defined measure of overall success was a combination of a successful outcome in ODI, neurologic status, disc height, no additional surgery classified as failure, and no serious device or device/surgical procedure-related adverse events at the 24-month follow-up. Patients who received the Maverick artificial disc had superior outcomes in overall success (73.5% vs. 55.3%) and in the component scores of ODI success (82.2% vs. 74.6% improved), back pain (improvement of 53.4 points vs. 49 points), and SF-36 Physical Component Summary score (17.0 vs. 14.3). Leg pain scores did not differ between the 2 groups. Global perceived effect ("completely recovered" or



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“much improved”) was higher in the Maverick group (78.1% vs. 67.4%). The Maverick group had fewer implant or surgical procedure-related adverse events (1% vs. 7%), and return-to-work intervals were reduced (median of 75 vs. 96 days). The percentage of patients who were working at 24 months was similar (74.1% vs. 73.4%). There were 2 implant removals in the Maverick group, one was considered to be related to an allergic reaction. Longer follow-up with this 2-piece metal-on-metal implant is needed, particularly in light of emerging complications (e.g., pseudotumor formation) with metal-on-metal hip implants. A case has been reported of a granulomatous mass surrounding a Maverick total disc replacement that caused iliac vein occlusion and spinal stenosis.

## FlexiCore

Preliminary results on the FlexiCore metal-on-metal intervertebral disc were presented from 2 of the sites involved in the investigational device trial in 2008. Results were reported for 76 patients enrolled at the 2 sites (out of the entire study cohort of 401 patients) who had been randomly assigned with a ratio of 2:1 to either FlexiCore or fusion control; 9 subjects did not receive the index surgery, 44 patients were treated with the artificial disc, and 23 patients were treated with fusion. Compared with fusion, placement of the artificial disc was associated with less blood loss (97 mL vs. 179 mL, respectively), reduced operating time (82 min vs. 179 min, respectively), and reduced length of hospital stay (2 vs. 3 days, respectively). Oswestry disability index and VAS pain scores were not significantly different between the groups. At 24 months, the Oswestry scores had decreased from 62 to 6 in the Flexicore group and from 58 to 12 in the fusion group. VAS scores decreased from 86 to 16 in the FlexiCore group and from 82 to 20 in the fusion group. Eight patients in each group had complications requiring interventional surgery.

## Other

In 2009, Berg et al. published an RCT of 1- and 2- level total disc replacement. Patients (n=152) with symptomatic degenerative disc disease in 1 or 2 motion segments between L3 and S1, with lower back pain as a predominant symptom, were randomly assigned to 1 of 3 total disc replacement devices available in Sweden (Charité, Prodisc, or Maverick, n=80) or to instrumented fusion (posterolateral or posterior lumbar interbody fusion, n=72). The randomization was stratified for number of levels, with 56% of total disc replacement patients having 1-level surgery compared to 46% of fusion patients. Only patients who did not have a preference to the type of treatment were enrolled in the trial, and they were informed of the result of randomization upon arrival at the hospital for surgery. No patient left the study when informed of the randomization, and there was 100% follow-up at the 1- and 2-year assessments. The primary outcome, which does not appear to be a validated measure, was a global assessment of back pain consisting of “total relief”, “much better”, “better”, “unchanged”, or worse. At both 1- and 2-year follow-up, 30% of patients in the disc replacement group reported being pain-free. In the fusion group, 10% reported being pain-free at 1 year and 15% were pain-free at 2 years. The total disc replacement group showed lower mean VAS for pain at 1 and 2 years (25.4 vs. 29.2, respectively) and had better outcome scores on a quality-of-life scale (EQ-5D) and the ODI at 1 year (19.5 vs. 24.9, respectively) but not the 2-year follow-up (20.0 vs. 23.0, respectively). The rate of complications was similar in the 2 groups, with 8 reoperations (10%) in the disc replacement group and 7 (9.7%) in the fusion group. The most common cause of reoperation in the disc replacement group was to fuse the index level that was believed to cause persistent or recurrent pain (5%). The most common cause of reoperation in the fusion group was operation at an adjacent level (7%). Twenty-two disc replacement patients underwent postoperative facet block due to remaining pain. Twenty



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fusion patients had their instrumentation removed due to persistent or recurrent pain. As of the 2-year follow-up, no differences were observed between 1-level and 2-level treatment. The investigators found no association between achievement of surgical goals (absence of mobility with fusion and maintenance of mobility with disc replacement) and clinical outcomes at 2 years.

The design of a U.S. multicenter clinical trial to evaluate the safety and effectiveness of the Aesculap Activ-L artificial disc has also been reported. The study is a single-blinded, randomized non-inferiority trial comparing Activ-L with a control artificial lumbar disc (Charité or ProDisc-L) for single-level degenerative disc disease of the lumbar spine. Following surgeon training with an initial 90 patients, it is expected that 324 patients will be randomly assigned in a 2:1 ratio. The patients will be followed for 5 years post-treatment.

## Adverse Events

Complications with artificial lumbar discs are emerging with longer-term follow-up. One study from Asia reported that clinical outcomes of both the Charité and the ProDisc were fairly good, but the facet joint of the index level and the disc at the adjacent level showed an aggravation of the degenerative process in a significant number of patients, regardless of the device used. Another study reported that progression of facet degeneration (29% of levels replaced with the ProDisc II) was associated with female gender, malposition of the prosthesis on the frontal plane, and 2-level total disc replacement. Analysis of postoperative pain patterns in 58 patients of 175 (33%) implanted with the ProDisc II showed facet joint pain in 22 (13%) and sacroiliac joint pain in 21 (12%). Another report describes late complications in 75 patients who had received an earlier generation SB Charité prosthesis. As all of the patients had been originally treated by other surgeons, the percentage of implant failure cannot be determined from this report. The mean interval between insertion and retrieval of the prosthesis was 8 years and 11 months (range of 3–16 years). The most frequent complications included subsidence (n=39), disc prosthesis too small (n=24), adjacent disc degeneration (n=36), degenerative scoliosis (n=11), facet joint degeneration (n=25), and metal wire breakage (n=10). The report indicated that good placement and good sizing of the disc prosthesis appeared problematic for many of the patients, adjacent disc degeneration was seen in many patients, and polyethylene wear with inflammatory fibrous tissue containing wear debris was observed. The report concluded that wear mechanisms of artificial discs may be similar to artificial hips and knees and that, due to nearby vascular structures and scar tissue from the original surgery, retrieval of an artificial disc prosthesis can be difficult and dangerous. Therefore, long-term health outcomes following disc implantation in young active patients may become a clinically significant issue.

In 2011, Guyer et al. reported 4 cases of a lymphocytic reaction to a metal-on-metal artificial disc (1 Kineflex-C cervical disc, 2 Kineflex-L lumbar discs, and 1 Maverick lumbar disc) that required revision. The mode of failure was determined to be compression of neural tissue or other adjacent structures by a soft-tissue mass. Three patients had a good outcome after the explantation and revision surgery; 1 patient continued to have residual symptoms related to the neural compression caused by the mass.

## Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received



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does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2008. The 4 reviewers disagreed with the policy statement that artificial intervertebral discs for the lumbar spine are investigational.

After consideration of the clinical input in 2008, it was concluded that due to limitations of the only 2 available RCTs (described here), combined with the marginal benefit compared to fusion, evidence is insufficient to determine whether artificial lumbar discs are beneficial in the short term. In addition, serious questions remain about potential long-term complications with these implants.

## Summary

Overall, the available scientific evidence remains insufficient to permit conclusions concerning the effect of this technology on the net health outcome. The 5-year results of the ProDisc-L randomized controlled trial provide evidence for the non-inferiority of artificial disc replacement. Superiority of ProDisc-L to circumferential fusion was achieved at 2, but not 5 years in this unblinded trial. At this time, the potential benefits of the artificial disc, such as faster recovery or reduced adjacent level disc degeneration, have not been demonstrated. In addition, considerable uncertainty remains about whether response rates will continue to decline over longer time periods, as well as the potential for long-term complications with these implants.

Evidence is insufficient to determine whether artificial lumbar discs improve outcomes in the short term, and questions remain about potential long-term complications with these implants. While some randomized trials have concluded that this technology is non-inferior to fusion, the potential benefits of artificial lumbar disc that would make non-inferiority sufficient to demonstrate clinical benefit have not been established. Therefore, artificial intervertebral discs for the lumbar spine are considered investigational.

## References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Artificial Intervertebral Disc: Lumbar Spine", 7.01.87, 09:2012.
2. Lemaire JP, Skalli W, Lavaste F et al. Intervertebral disc prosthesis. Results and prospects for the year 2000. *Clin Orthop Relat Res* 1997; (337):64-76.
3. Hochschuler SH, Ohnmeiss DD, Guyer RD et al. Artificial disc: preliminary results of a prospective study in the United States. *Eur Spine J* 2002; 11 Suppl 2:S106-10.
4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial vertebral disc replacement. TEC Assessments 2005; Volume 20, Tab 1.
5. Blumenthal S, McAfee PC, Guyer RD et al. A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part I: evaluation of clinical outcomes. *Spine (Phila Pa 1976)* 2005; 30(14):1565-75; discussion E387-91.
6. U.S. Food and Drug Administration. Draft of PRODISC-L Total Disc Replacement package insert. Available online at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf5/P050010c.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010c.pdf). Last accessed August, 2011.
7. U.S. Food and Drug Administration. PRODISC-L Summary of Safety and Effectiveness Data. Available online at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf5/P050010b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010b.pdf). Last accessed August, 2011.
8. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial lumbar disc replacement. TEC Assessments 2007; Volume 22, Tab 2.
9. van den Eerenbeemt KD, Ostelo RW, van Royen BJ et al. Total disc replacement surgery for symptomatic degenerative lumbar disc disease: a systematic review of the literature. *Eur Spine J* 2010; 19(8):1262-80.

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# BlueCross BlueShield of Louisiana

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## Artificial Intervertebral Disc: Lumbar Spine

Policy # 00145

Original Effective Date: 01/31/2005

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10. Yajun W, Yue Z, Xiuxin H et al. A meta-analysis of artificial total disc replacement versus fusion for lumbar degenerative disc disease. *Eur Spine J* 2010; 19(8):1250-61.
11. Guyer RD, McAfee PC, Banco RJ et al. Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: five-year follow-up. *Spine J* 2009; 9(5):374-86.
12. Putzier M, Funk JF, Schneider SV et al. Charite total disc replacement--clinical and radiographical results after an average follow-up of 17 years. *Eur Spine J* 2006; 15(2):183-95.
13. Scott-Young MN, Lee MJ, Nielsen DE et al. Clinical and radiological mid-term outcomes of lumbar single-level total disc replacement. *Spine (Phila Pa 1976)* 2011 [Epub ahead of print].
14. Zigler J, Delamarter R, Spivak JM et al. Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. *Spine (Phila Pa 1976)* 2007; 32(11):1155-62; discussion 63.
15. Zigler JE. Five-year results of the ProDisc-L multicenter, prospective, randomized, controlled trial comparing ProDisc-L with circumferential spinal fusion for single-level disabling degenerative disk disease. *Semin Spine Surg* 2012; 24(1):25-31.
16. Delamarter R, Zigler JE, Balderston RA et al. Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement compared with circumferential arthrodesis for the treatment of two-level lumbar degenerative disc disease: results at twenty-four months. *J Bone Joint Surg Am* 2011; 93(8):705-15.
17. Schoenfeld AJ. Commentary on an article by Rick Delamarter, MD, et al.: "Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement compared with circumferential arthrodesis for the treatment of two-level degenerative lumbar disc disease. Results at twenty-four months". *J Bone Joint Surg Am* 2011; 93(8):e41.
18. Tropiano P, Huang RC, Girardi FP et al. Lumbar total disc replacement. Seven to eleven-year follow-up. *J Bone Joint Surg Am* 2005; 87(3):490-6.
19. Hannibal M, Thomas DJ, Low J et al. ProDisc-L total disc replacement: a comparison of 1-level versus 2-level arthroplasty patients with a minimum 2-year follow-up. *Spine (Phila Pa 1976)* 2007; 32(21):2322-6.
20. Gornet MF, Burkus JK, Dryer RF et al. Lumbar disc arthroplasty with MAVERICK disc versus stand-alone interbody fusion: a prospective, randomized, controlled, multicenter investigational device exemption trial. *Spine (Phila Pa 1976)* 2011; 36(25):E1600-11.
21. Berry MR, Peterson BG, Alander DH. A granulomatous mass surrounding a Maverick total disc replacement causing iliac vein occlusion and spinal stenosis: a case report. *J Bone Joint Surg Am* 2010; 92(5):1242-5.
22. Sasso RC, Foulk DM, Hahn M. Prospective, randomized trial of metal-on-metal artificial lumbar disc replacement: initial results for treatment of discogenic pain. *Spine (Phila Pa 1976)* 2008; 33(2):123-31.
23. Berg S, Tullberg T, Branth B et al. Total disc replacement compared to lumbar fusion: a randomised controlled trial with 2-year follow-up. *Eur Spine J* 2009; 18(10):1512-9.
24. Berg S, Tropp HT, Leivseth G. Disc height and motion patterns in the lumbar spine in patients operated with total disc replacement or fusion for discogenic back pain. Results from a randomized controlled trial. *Spine J* 2011; 11(11):991-8.
25. Yue JJ, Mo FF. Clinical study to evaluate the safety and effectiveness of the Aesculap Activ-L artificial disc in the treatment of degenerative disc disease. *BMC Surg* 2010; 10:14.
26. Shim CS, Lee SH, Shin HD et al. CHARITE versus ProDisc: a comparative study of a minimum 3-year follow-up. *Spine (Phila Pa 1976)* 2007; 32(9):1012-8.
27. Park CK, Ryu KS, Jee WH. Degenerative changes of discs and facet joints in lumbar total disc replacement using ProDisc II: minimum two-year follow-up. *Spine (Phila Pa 1976)* 2008; 33(16):1755-61.
28. Siepe CJ, Korge A, Grochulla F et al. Analysis of post-operative pain patterns following total lumbar disc replacement: results from fluoroscopically guided spine infiltrations. *Eur Spine J* 2008; 17(1):44-56.
29. Punt IM, Visser VM, van Rhijn LW et al. Complications and reoperations of the SB Charite lumbar disc prosthesis: experience in 75 patients. *Eur Spine J* 2008; 17(1):36-43.
30. Guyer RD, Shellock J, MacLennan B et al. Early failure of metal-on-metal artificial disc prostheses associated with lymphocytic reaction: diagnosis and treatment experience in four cases. *Spine (Phila Pa 1976)* 2011; 36(7):E492-7.
31. Chou R, Loeser JD, Owens DK et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine (Phila Pa 1976)* 2009; 34(10):1066-77.
32. Chou R, Baisden J, Carragee EJ et al. Surgery for low back pain: a review of the evidence for an American Pain Society Clinical Practice Guideline. *Spine (Phila Pa 1976)* 2009; 34(10):1094-109.
33. National Institute for Health and Clinical Excellence (NICE). Prosthetic intervertebral disc replacement. IP Guidance Number: IPG100. 2004.

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34. National Institute for Health and Clinical Excellence (NICE). Prosthetic intervertebral disc replacement in the lumbar spine (IPG306). 2009. Available online at: <http://www.nice.org.uk/nicemedia/pdf/IPG306Guidance.pdf>. Last accessed August, 2011.
35. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Lumbar Artificial Disc Replacement (LADR) (150.10). 2007. Available online at: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=313&ncdver=2&CoverageSelection=National&Keyword=lumbar+artificial+disc&KeywordLookUp=Title&KeyWordSearchType=And&id=170&bc=gAAAAABAAAA&>.
36. Centers for Medicare and Medicaid Services (CMS). Change request 5727, CMS Manual system. September 11, 2007. Available online at: <http://www.cms.hhs.gov/Transmittals/Downloads/R75NCD.pdf>. Last accessed August, 2011.
37. Centers for Medicare and Medicaid Services (CMS). Medicare Learning Network Matters. 2007. Available online at: <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5727.pdf>. Last accessed August, 2011.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0163T, 0164T, 0165T, 22857, 22862, 22865
HCPCS	No codes
ICD-9 Diagnosis	722.10, 722.2
ICD-9 Procedure	84.65, 84.68

## Policy History

Original Effective Date: 01/31/2005  
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12/07/2004 Medical Director review  
 12/21/2004 Medical Policy Committee review  
 01/31/2005 Managed Care Advisory Council approval  
 07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged. Format revision. No change to policy statement.  
 01/01/2007 Medical Director review  
 01/17/2007 Medical Policy Committee approval. Coverage eligibility unchanged.

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02/13/2008	Medical Director review
02/20/2008	Medical Policy Committee approval
02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee approval. No change to coverage.
02/04/2010	Medical Director review
02/17/2010	Medical Policy Committee approval. No change to coverage.
02/03/2011	Medical Policy Committee review
02/16/2011	Medical Policy Implementation Committee approval. No change to coverage.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. No change to coverage.
01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. No change to coverage.
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date:	01/2015

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. reference to federal regulations.

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